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RECORD OF ORAL HEARING
UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

Appeal 2008-1869
Application 09/845,042
Technology Center 1600

Oral Hearing Held: July 10, 2008

Before DONALD E. ADAMS, RICHARD M. LEBOVITZ and
MELANIE L. McCOLLUM, *Administrative Patent Judges*.

ON BEHALF OF THE APPELLANTS:

ANDREW J. PATCH, ESQUIRE
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The above-entitled matter came on for hearing on Thursday, July 10, 2008, commencing at 9:01 a.m., at the U.S. Patent and Trademark Office, 600 Dulany Street, Alexandria, Virginia, before Jennifer M. O'Connor, Notary Public.

1 THE CLERK: Good morning. Calendar number 28, Mr. Patch.

2 JUDGE ADAMS: Good morning, Mr. Patch.

3 MR. PATCH: Good morning, Your Honor.

4 JUDGE ADAMS: We're familiar with your issues. You have 20
5 minutes and if you would begin by spelling your name into the record for us.

6 MR. PATCH: Sure. It's Andrew, A-n-d-r-e-w, J., middle initial,
7 Patch, P-a-t-c-h, with the firm of Young & Thompson. May it please the
8 board, the only issues remaining to be resolved by Your Honors in this
9 appeal are new matter questions. There are five recitations considered by
10 the Examiner to constitute new matter which appear variously in the four
11 independent claims that are pending and on appeal.

12 The one which appears in all four of the independent claims is the
13 phrase "for maximum of three days," which references the culture time, so
14 we'll start with that one. And, of course, I invite your questions at any time
15 during my -- during my speech or presentation.

16 The phrase "maximum of three days" does not appear *ipsis verbis* in
17 the Specification as filed, but of course, that's not required for compliance
18 with the written description requirement of 112, first paragraph. We do
19 think that it is very abundantly supported throughout the Specification in the
20 general disclosure and the original claims and in the example.

21 There are a number of examples which recite culturing these cells for
22 three days, which we believe in and of itself supports the recitation of a
23 maximum of three days. Certainly to the extent of the upper limit of that
24 recitation, to the extent that you view that recitation as being a range, that is,
25 even if the Specification were viewed as teaching culturing for a longer time,
26 it doesn't seem to me to be any different than the case where you disclose a

1 broader range and a narrower range and the Applicant, of course, is entitled
2 to limit his claims to the narrower range if he feels that's necessary for
3 whatever reason to avoid the prior art or to overcome an enablement
4 rejection.

5 JUDGE ADAMS: So your Specification starts out with within three
6 days of culture. Then further along in your Specification, you give some
7 examples where you take cells two days after culture or three days after
8 culture, and you're arguing it would be -- you set these endpoints. You said
9 within three days you should have support for the maximum of three days?

10 MR. PATCH: Exactly.

11 JUDGE LEBOVITZ: What was the Examiner's problem with that?

12 MR. PATCH: It's not totally clear to me. When I was rereading the
13 Examiner's Answer, I remember having thought that he felt the Specification
14 was not -- did not support saying nothing more than three days. When I
15 reread the Examiner's Answer, I started to get the impression that he might
16 have a problem with it to the extent that it encompassed one day or
17 something toward the lower end of that range.

18 There I don't think that that concern is valid on the record. I think the
19 phrase "within three days" that we find several times in the Application
20 supports the range. To the extent he was concerned with it, how -- and
21 what's the minimum amount of time you could utilize to culture these cells
22 and obtain the characteristics claimed, I think that would be more of a scope
23 of enablement type of an issue.

24 We did have a non-enablement rejection at the outset of the appeal
25 and that was withdrawn in the Examiner's Answer. But even there, I think,
26 it's -- I mean, it would be a different issue, one of enablement. And I don't

1 think on this record it would be a valid issue in the sense that the claims
2 already by their terms are directed to producing cells having these
3 characteristics. So if you were to perform the process for too short a time,
4 by definition you would not be performing the claimed method.

5 Three of the four independent claims contain the recitation in the
6 absence of IL-4, Interlukin 4, and the fourth one arguably contains it
7 implicitly by contrasting the characteristics of the produced cells to cells that
8 are produced in the presence of IL-4.

9 There again, it's an instance where we admittedly do not have *ipsis*
10 *verbis* or explicit antecedent basis in the Specification as filed, but we feel
11 that it's very clear to a skilled artisan from reading the Application that this
12 is part of what we invented. We didn't pull IL-4 out of thin air in terms of
13 introducing it in the context of a negative limitation. Rather the entire
14 Specification contrasts the dendritic cells that are produced according to the
15 invention with those made in the presence of IL-4.

16 And that's the whole approach taken in terms of characterizing the
17 invention. Here's what you get, according to the invention, when you use
18 type 1 interferon with this GM-CSF. Here's what you get on the other hand,
19 not according to the invention, when you use IL-4 together with this GM-
20 CSF.

21 There were a number of passages we put in our Brief, in our Reply
22 Brief. We should have put them all. In combing through the Specification
23 to prepare for argument, I noticed one or two others. There's a mention on
24 page 28 of utilizing interferon and GM-CSF. It uses the phrase "instead of
25 IL-4 and GM-CSF," which may be as close as we come to *ipsis verbis*
26 support for this recitation.

1 And there's numerous recitations, some of which I believe we've cited
2 to in the Brief, using the phrasing "either interferon GM-CSF or IL-4 GM-
3 CSF."

4 JUDGE ADAMS: As you explain, your culture cells, you filter two
5 different populations of cells in the presence or in the absence of IL-4 and
6 then compare and contrast the result of those two sets of cells, right?

7 MR. PATCH: Right.

8 JUDGE ADAMS: Go ahead.

9 MR. PATCH: Those are the first two. We then have -- the phrase
10 "within three days" was separately objected to as being new matter and
11 there, I think, we actually have not only implicit support, but also the
12 explicit *ipsis verbis* support.

13 JUDGE ADAMS: Within three days appears in the summary of your
14 invention and in at least one of your original claims?

15 MR. PATCH: That's right, it appears in the original claim 2, Your
16 Honor. I'm glad you picked that up because I'm not sure that we were on the
17 ball in terms of citing that in our Brief, as well as in the summary, as you
18 note, and several other places in the Specification, as further supported by
19 the reference of two to three days in several instances, which leaves, I
20 believe, only the two numerical range limitations, which --

21 JUDGE ADAMS: You're arguing for both of those as you disclose a
22 set of ranges? You disclose experiments that use a particular endpoint in
23 *In re Wertheim* to support your position on that?

24 MR. PATCH: That's right, Your Honor.

25 JUDGE ADAMS: Anything else?

1 MR. PATCH: Well no, that's essentially it. Those two ranges appear
2 in, I believe, only one of the four independent claims and also I believe in at
3 least one of the dependent claims. But it is an argument premised on *In re*
4 *Wertheim*. It seems factually very similar there, if anything, I would
5 suggest, perhaps even a bit easier. Because my recollection of that case was
6 that the parent Application had a range of 25 to 60 and an example at 36.
7 And the CCPA found that supported subsequently a claimed range of 35 to
8 60, where they actually had an endpoint that wasn't specifically mentioned.

9 Here we're using endpoints, all of which are specifically described,
10 not only in the context of an example, but also, I believe, in the context of
11 narrower preferred ranges?

12 JUDGE LEBOVITZ: Did the Examiner respond to the *Wertheim*
13 argument?

14 MR. PATCH: He did. He cited several cases in the Examiner's
15 Answer which I don't think are as on-point as is *In re Wertheim*. He gave
16 some discussion of another CCPA case of *In re Smith* which I think had to
17 do with claiming a specific compound embraced by a genus but where there
18 was no disclosure of that specific compound in, I don't know whether it was
19 the Application as filed or a priority Application. It's always the same
20 question of course.

21 But in *Wertheim*, that was one of the cases that was discussed in some
22 length and distinguished. Of course, to the extent there is any conflict
23 between those two cases, *Wertheim* would control since the CCPA always
24 sat in banks. So, whatever their latest word was was the controlling word.
25 But I don't think there really is any conflict between those two cases and I

1 don't think the CCPA viewed there as being a conflict between the two
2 cases.

3 JUDGE LEBOVITZ: So there was no subsequent case to work on
4 that you cited that conflicted with the range, written description law?

5 MR. PATCH: Well, there were two subsequent cases that he cited, but
6 I don't think that they did conflict with that range, the *Wertheim* range law.
7 So far as I know, that *Wertheim* law is still controlling and my observation
8 has been that the board tends to look to that. Certainly we do from the
9 Applicant's side when this type of question arises.

10 The Examiner -- I recall in his Examiner's Answer -- did make a
11 comment saying that this assessment of new matter is always fact specific
12 and there's no sort of magic omnibus rule, and I agree that it's inappropriate
13 to view *Wertheim* in that way. *Wertheim* itself says it's case by case and fact
14 specific.

15 But the Examiner makes the suggestion that I don't think is supported
16 on the record, which is that in narrowing to these recited ranges that are in
17 question, this is somehow critical for enablement and that a broader range
18 would not be enabled and therefore this range should be viewed as more
19 suspect under the written description standard.

20 But when you look at the other three independent claims, they have
21 the broader ranges which are explicitly supported in the original disclosure,
22 and those ranges are considered to be enabled. But I don't think on this
23 record that our narrowing changes the complexion of the claim from the
24 standpoint of being on one side or the other of the enablement standard.

25 JUDGE LEBOVITZ: And since they're encompassed or described,
26 there's an expectation that range would give you the same results?

1 MR. PATCH: I agree, Your Honor.

2 JUDGE ADAMS: Okay, anything else?

3 MR. PATCH: That's all I have. If Your Honors don't have any other
4 questions --

5 JUDGE ADAMS: Questions? Okay, thank you.

6 MR. PATCH: Thank Your Honors.

7 (Whereupon, at 9:13 a.m., the proceedings were concluded.)

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